

**UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC**

FSIS NOTICE

13-16

2/11/16

**PUBLIC HEALTH REGULATIONS AND ALERTS FOR USE IN DETERMINING INSPECTION
PROGRAM PERSONNEL (IPP) ACTIONS AND FOOD SAFETY ASSESSMENT
SCHEDULING IN MEAT, POULTRY ESTABLISHMENTS AND EGG PRODUCT PLANTS**

I. PURPOSE

A. This notice cancels FSIS Notice 12-16, issued on 2/8/16, and reissues its content with corrections and additional information.

B. This notice defines the new Public Health Regulation (PHR) alerts in the Public Health Information System (PHIS) and instructs inspection program personnel (IPP) how to respond when there is a pattern of repetitive non-compliances at the plant to which they are assigned. Each month the Office of Data Integration and Food Protection (ODIFP) will use the results of inspection tasks to calculate a PHR non-compliance rate for each meat and poultry official establishment as well as egg products plants. IPP will then compare the establishment's non-compliance (NR) rate to two set cut points. A PHR alert will be issued to IPP when an establishment has a non-compliance rate that is elevated and is at or exceed the Noncompliance Cut Point for Early Warning (see III.B., below).

C. When IPP receive an Early Warning alert, they are to take the steps set out in this notice. The alert will appear on the IPP dashboard with a list of reference numbers for the NRs that caused the alert to be generated.

D. Establishments with a PHR NR rate that exceeds the Noncompliance Cut Point for *Public Health Risk Evaluation (PHRE)/Food Safety Assessment (FSA) Scheduling* (see III. B., below) will be listed in the proposed for cause PHRE/FSA monthly schedule, which is provided by ODIFP to Office of Field Operations (OFO) District Offices. A District Office with a plant on the PHRE/FSA scheduling list is to assign an Enforcement, Investigations, and Analysis Officer (EIAO) to perform a PHRE and make a decision on scheduling a FSA at the establishment.

E. This notice also includes updated instructions to EIAOs on sharing PHR information with establishments at Food Safety Assessment (FSA) entrance meetings. In addition, it:

1. Instructs IPP in all meat, poultry establishments, and egg products plants on how to review the PHR alert list; and
2. Instructs Frontline Supervisors (FLS) to provide guidance to IPP about findings and trends in the establishment when an alert is generated.

DISTRIBUTION: Electronic

NOTICE EXPIRES: 3/1/17

OPI: OPPD

II. BACKGROUND

A. ODIFP analyzes noncompliance data in PHIS from establishments that have received NRs that cite the regulations on the PHR list. ODIFP annually reviews the regulations designated as “Public Health Regulations” (PHRs), which are listed on the [Public Health Regulations webpage](#), and makes updates as needed to better reflect NRs associated with public health hazards.

B. FSIS uses a three-step method to identify PHRs. The Agency:

1. Defines a set of evaluation criteria for selecting a candidate list of regulations;
2. Develops a list of candidate regulations that are relied upon in verifying food safety process control; and
3. Selects a subset of the candidate regulations that, ODIFP has determined, are out of compliance at an elevated rate in establishments that have had *Salmonella*, *E. coli* O157:H7, *non-O157 STEC*, *Listeria monocytogenes (Lm)*, or *Campylobacter* positives, or in establishments without positives that had another deficiency that resulted in an enforcement action.

C. Details on how the evaluation criteria for the PHRs were established are in the [FY2016 Public Health Regulations](#) report. The higher the NR rate is at an establishment, the more likely the establishment will produce product that will have a negative impact on the public health.

III. RECEIPT OF A PHR ALERT

A. IPP will receive an alert in the IPP dashboard in PHIS when the number of NRs issued to the establishment reaches the noncompliance Cut Point for Early Warning. The information in the NRs is to be used by IPP to identify trends in noncompliance and is based on the verification data entered into PHIS in performing daily activities. The alert will be in the following form:

Establishment Number	Circuit Number	Establishment Type	Number of PHRs Verified	Number of PHR Noncompliances	PHR Noncompliance Rate	Noncompliance Cut Point For Early Warning	Noncompliance Cut Point For PHRE/FSA Scheduling	Status	EstID
----------------------	----------------	--------------------	-------------------------	------------------------------	------------------------	---	---	--------	-------

B. The following describes the information in each column of the alert:

Establishment Number	M, P, V, or G with number
Circuit Number	XXXX
Establishment Type	Processing or Combination
Number of PHRs Verified	Derived from the regulations checked while performing tasks in PHIS
Number PHR NRs	NRs by number will be shown as part of the alert
PHR Noncompliance Rate	This is the number used to determine issuance of the alert. The number shown in this column is current rate. If this rate is higher than the cut point for early warning, the alert is issued in PHIS. If this rate reaches a rate that is higher than the cut point for PHRE/FSA scheduling, a PHRE is to be scheduled. It is derived by

	dividing the number PHR noncompliances by the number of PHRs verified and multiplied by 100.
Noncompliance Cut Point for Early Warning	The number reached that triggered the alert. The Noncompliance Rate Cut Point for Early Warning for FY16 is set at 5.32 in Combination establishments and at 2.97 in Processing establishments. These rates will likely change from year to year.
Noncompliance Cut Point For PHRE/FSA Scheduling	As set by Fiscal Year (FY) 2016 Public Health Regulations
Status	Elevated, but below PHRE cut point will be displayed in IIC alert
EstID	

C. An FSIS e-mail mailbox will be set up for 90 days following the release of the alert. Personnel receiving the alert will have the opportunity to provide feedback on such matters as the usefulness of the alert and ways in which the alert can be improved. This feedback will be used in the development and implementation of other alerts.

III. IPP RESPONSIBILITIES IN RESPONSE TO PHR ALERTS

A. IPP are to review this notice to familiarize themselves with the FY2016 PHRs so that they can be aware of how FSIS determines the public health-related NR rates. IPP can find the FY2016 PHR list and cut points on the FSIS Data Analysis and Reporting: [Public Health Regulations webpage](#).

B. Once IPP in meat and poultry establishments and egg product plants receive an alert, they are to:

1. Review the PHR alert and review NRs that have been linked or associated with the alert;

NOTE: IPP may run a PHIS Report to view the status of the individual establishment. The report is titled “PHR Noncompliances for an Establishment” and may be found in the report tab of PHIS. The PHIS Report provides more specific information about the NRs associated with the PHR alert. This information is particularly useful to relief personnel and to IPP who rotate to the establishment. FLSs may run a summary of all establishments in their circuit from the “PHR Noncompliance for a Circuit” report.

2. Discuss their analysis of the PHR alert, the PHIS Report, and the associated NRs with supervisory personnel to determine whether a trend of ineffective corrective actions or repetitive NRs exists at the establishment, and what actions to take based upon their analysis, including developing a plan that may include targeted additional directed tasks. If additional tasks are performed, IPP are to mark scheduled tasks that were not completed as “Not Performed” by following the instructions in [FSIS Directive 13,000.1, Scheduling In-Plant Inspection Tasks in the Public Health Information System \(PHIS\)](#);
3. Discuss with the establishment at a weekly meeting the findings and information that underlie the PHR alert and any actions that the IPP intend to take based on their analysis of the findings and information.

4. Once they have implemented their plan, assess whether a trend of noncompliance is continuing, and whether the corrective actions that the establishment implemented have proven to be ineffective. IPP will inform the supervisor of their determination.

C. IPP, at the direction of supervisory personnel, may perform directed tasks to determine whether a trend is continuing, and whether corrective actions performed by the establishment are effective. If additional tasks are performed, IPP could mark scheduled tasks as Not Performed by following the instructions in [FSIS Directive 13,000.1](#).

IV. FLS RESPONSIBILITIES IN RESPONSE TO PHR ALERTS

Supervisory personnel are to review the PHR alert reports, MOIs, and associated NRs and have open communication with the inspection teams to be aware of establishments that have demonstrated PHR noncompliance or failure to implement effective corrective actions.

V. FOOD SAFETY ASSESMENT ENTRANCE MEETINGS

A. As per [FSIS Directive 5100.4](#), *Enforcement, Investigations and Analysis Officer (EIAO) Public Health Risk Evaluation (PHRE) Methodology*, EIAOs are to conduct a PHRE at establishments listed on the proposed “for cause” FSA schedule. EIAOs are to perform PHREs to determine whether to conduct a FSA, as described in [FSIS Directive 5100.1](#), *Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment Methodology*; to take an administrative enforcement action as described in [FSIS Directive 5100.3](#), *Administrative Enforcement Reporting (AER) System*; or to take no action because neither an enforcement action or an FSA is needed.

B. At entrance meetings, EIAOs are to meet with establishment management as described in [FSIS Directive 5100.1](#) and discuss PHRs. The EIAO may refer establishment management to the [Review of Criteria for Public Health Related Non Compliance Records](#), from the National Advisory Committee on Meat and Poultry Inspection (NACMPI) Subcommittee, for more detailed information regarding the PHRs review criteria.

C. Information pertaining to the IPP alerts and instruction will not need to be discussed.

VI. DATA ANALYSIS

ODIFP is to periodically analyze the PHR selection criterion and the subsequent FSAs performed to evaluate the effectiveness of this criterion. ODIFP is also to analyze data gathered from this process to further refine the methods for selecting PHRs and prioritizing establishments for FSAs.

VII. QUESTIONS

Refer questions regarding this notice to the Risk, Innovations, and Management Staff through [askFSIS](#) or by telephone at 1-800-233-3935. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field: Enter **13-16**
Question Field: Enter question with as much detail as possible.
Product Field: Select **General Inspection Policy** from the drop-down menu. Category Field: Select **EIAO Methodology** from the drop-down menu.
Policy Arena: Select **Domestic (U.S.) Only** from the drop-down menu.

When all fields are complete, press **Continue** and at the next screen press **Finish Submitting**

Question.

NOTE: Refer to [FSIS Directive 5620.1](#), *Using askFSIS*, for additional information on submitting questions.

A handwritten signature in black ink, appearing to read "David J. Schubert". The signature is fluid and cursive, with the first name "David" being the most prominent.

Assistant Administrator
Office of Policy and Program Development